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ORIGINAL ARTICLE

Design and evaluation of an independent 4-week, exosuit-assisted, post-stroke community walking program

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Abstract

Chronic impairment in the paretic ankle following stroke often requires that individuals use compensatory patterns such as asymmetric propulsion to achieve effective walking speeds needed for community engagement. Ankle exosuit assistance can provide ankle biomechanical benefit in the lab, but such environments inherently limit the amount of practice available. Community walking studies without exosuits can provide massed practice and benefit walking speed but are limited in their ability to assist proper mechanics. In this study, we combined the positive aspects of community training with those of exosuit assistance. We developed and evaluated a community Robotic Exosuit Augmented Locomotion (cREAL) program. Four participants in the chronic stage of stroke independently used our community ankle exosuit for walking in the community 3–5 days/week for 4 weeks. We performed lab evaluations before and after the 4-week program. Two participants significantly improved their unassisted paretic propulsion by an average of 27% after the program and walked on average 4001 steps/day more in the week following the program. Despite the small number of participants, this study provides preliminary evidence for the potential of exosuits to augment gait training and rehabilitation in the community.

KEYWORDS
community, exosuit, gait, propulsion, rehabilitation, stroke, training

INTRODUCTION

Hemiparetic gait following stroke is characterized by slow and inefficient walking that is prohibitive toward community engagement and quality of life.[1–6] Following therapy, some individuals can achieve walking speeds greater than 0.8 m/s, classifying them as unlimited community ambulators;[7,8] however, these speeds are often achieved through maladaptive compensatory patterns rather than proper ankle biomechanics[9–11] and can be prohibitive to active and safe community ambulation.[12] While therapy has been shown to improve functional

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outcomes like gait speed, community stepping, and aerobic function, proper restoration of paretic ankle function remains a rehabilitation challenge.[13]

For individuals post-stroke, exoskeletons and exosuits offer an opportunity to complement traditional therapy by providing targeted assistance to the paretic ankle to promote more typical gait mechanics and encourage neuromuscular rehabilitation.[14–17] Exosuits can provide immediate within-session locomotor benefits (i.e., orthotic benefit), including faster walking speeds, reduced energy use, and reduced maladaptive compensatory patterns.[14,16–18] Nevertheless, the majority of exosuit studies are from a single session in which participants have limited opportunity to train with the device and harness its potential benefits through continued use.

Focused training and practice are important for stroke recovery[19] and effective exosuit use.[20] Thus, more recent studies in the lab/clinic have investigated the effect of massed, multisession, ankle exosuit-assisted stepping practice in post-stroke gait.[13,15] An in-lab, consideration-of-concept trial study in which a post-stroke participant was provided 5 days of progressive speed training with an ankle-assisting exosuit showed improvements in unassisted walking speed, distance, and paretic propulsion after training (i.e., therapeutic effect).[15] Similarly, a multiweek, high-intensity gait training program with an ankle exosuit showed improvements in walking speed, distance, and symmetry of hip and knee flexion/extension for five participants post-stroke.[13] These results are exciting, yet these studies still fall within the traditional model of having participants train with a device for massed stepping proactive only when working directly with a therapist in a lab or clinic environment. There is an opportunity to extend the paradigm of exosuit-assisted massed stepping practice to the community. This new model can potentially overcome issues related to underdosing of therapy and the lack of sufficient mechanisms to allow for robust, high-quality practice in the home and community setting needed to aid in neurorecovery.[19,21,22]

Community-based gait training without exosuit assistance has been shown to improve walking distance and speed.[22,23] In addition to mitigating some challenges with the logistics of scheduling and transportation to clinics, self-directed community walking programs enable independence that benefits motivation,[24–26] improves walking functions,[27,28] and increases social participation.[29] The addition of exosuit assistance to a community walking program has the potential to provide additional support for improved gait mechanics and paretic propulsion that are crucial for a holistic recovery. Furthermore, exosuits may partially offset the high energetic cost of walking in post-stroke individuals,[16] which leads to physical inactivity.[30–34]

Our overall goal with this study was to develop and evaluate a community Robotic Exosuit Augmented Locomotion (cREAL) program that fills the research gap between exosuit-assisted, in-clinic therapy and community walking training.

Our first objective was to make feasible and implement the multiweek, independent, exosuit-assisted community walking program for individuals post-stroke. To satisfy feasibility requirements, participants needed to use the active exosuit system safely and effectively in a community setting without direct supervision. Furthermore, we needed to monitor the daily status of participants, including walking activity (e.g., day and duration), safety (e.g., no self-reported falls), and compliance to administrative controls (e.g., the participant is at a safe location). In response, for this study, we designed the cREAL walking program, developed a lightweight and independently donnable community ankle exosuit, and created a cloud-connected mobile application for user operation, data communication, and study safety and protocol compliance. We then implemented the study and tested participants in the chronic stage of stroke.

The second objective was to assess biomechanical outcomes and rehabilitation potential of the cREAL walking program through lab-based assessments. We evaluated the ability of participants to receive immediate within-session benefit on paretic propulsion from the exosuit (i.e., orthotic effect). We also quantified the training effect of the exosuit-assisted, community walking program on unassisted paretic propulsion (i.e., therapeutic effect) by comparing the paretic propulsion from the post-training evaluation to the pre-training evaluation. To assess the effect of the walking program on general walking engagement, we recorded participant step count before, during, and after the walking program. Finally, we developed a learning-based model that used data from body-worn sensors to estimate participants' paretic propulsion in the community over the course of the walking program.

METHODS AND MATERIALS

Overview

The goal of this study was to implement and evaluate an ankle exosuit-assisted, community walking program. We leveraged experience from exosuit work in the lab[16,17] to develop a community exosuit that provided reliable and effective dorsiflexion (DF) and plantarflexion (PF) assistance and could be used independently by individuals post-stroke. We designed the cREAL walking program that incorporated three main components: screening and training, an independent community certification (ICC), and a 4-week unsupervised community walking program (Figure 1). Finally, we performed lab-based biomechanical evaluations before and after the community walking program to evaluate the effectiveness and rehab potential of the cREAL walking program.

All participants provided written informed consent prior to participating in the study. The study was approved by the Institutional Review Boards of Harvard Longwood Area Institutional Review Board and all methods were carried out in accordance with the approved study protocol #IRB16-1845.

Community exosuit

To achieve safety and design simplicity, the exosuit generated passive DF assistance with a compliant PEEK (polyetheretherketone) rod, which had an effective torsional stiffness of 0.27 Nm/degree and a neutral angle of 5 degrees (Figure 2). The exosuit generated active PF assistance with a rope-driven actuator, which could provide up to 300 N tensional force and 24 Nm torque around the ankle. The magnitude and timing of the PF assistance applied a similar

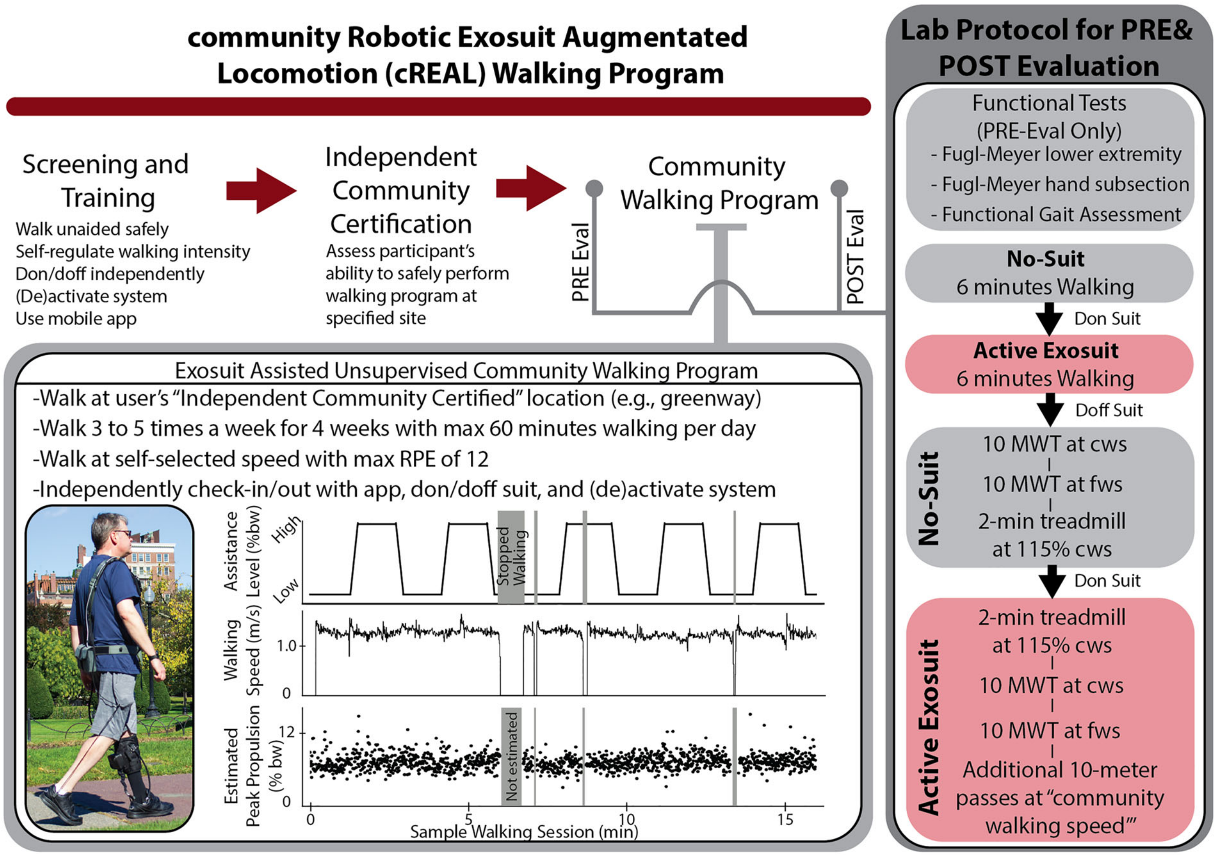

FIGURE 1 Overview of community Robotic Exosuit Augmented Locomotion (cREAL) walking program. To evaluate the effectiveness of the program, lab-based evaluations were performed within 7 days before and 7 days after the walking program. Exosuit sensor data from a representative walking session are shown including periods where participants stopped walking. Abbreviations: %bw, % body weight; 10 MWT, 10-meter walking test; cws, comfortable walking speed; fws, fast walking speed.

operating principle to past designs[16,17] while accounting for the antagonist torque from passive DF assistance (Figures S1 and S2).

The compliant PEEK rods provided additional shape stability for holding the soft flexible calf wrap in place while the magnetic buckle and hook-and-loop straps could be fastened with the nonparetic hand and minimal assistance from the paretic hand. All sensor components and connections were permanently fixed to the exosuit and required no additional donning. The design enabled post-stroke participants to don the exosuit independently and without specialized tools.

cREAL walking program

The cREAL walking program incorporated screening and training, an ICC, and a 4-week unsupervised community walking program (Figure 1).

Screening and training

Enrollment in the study was based on convenience sampling and all participants were in the chronic stage of stroke and had participated in prior lab studies using a similar exosuit. Given the proof-of-concept nature of this study and safety priority, participants were screened for the ability to walk safely in potentially distractible environments and were known to be unlimited community ambulators. Participants were not engaged in ongoing therapy during the study.

Participants visited the lab for a 3-h screening and training session. To complete screening and training, participants had to demonstrate an ability to safely walk unaided while perceiving and self-regulating walking intensity to keep their rate of perceived effort (RPE) less than 12,[35,36] independently don and doff the exosuit, (de)activate the exosuit, and use the mobile application for attestation and monitoring of participant's safety and compliance (Figures S3, S5, and S6).

Independent community certification

The ICC was the formal procedure by which the research team evaluated the participants' ability to safely perform the community walking program at the specified location. The participant performed a mock mini-session to demonstrate their ability to perform the steps for independent and unsupervised exosuit-assisted community walking. When successfully completed, the team physical therapist certified that the participant was eligible for the program at the specific location (Supporting Text, Figure S4).

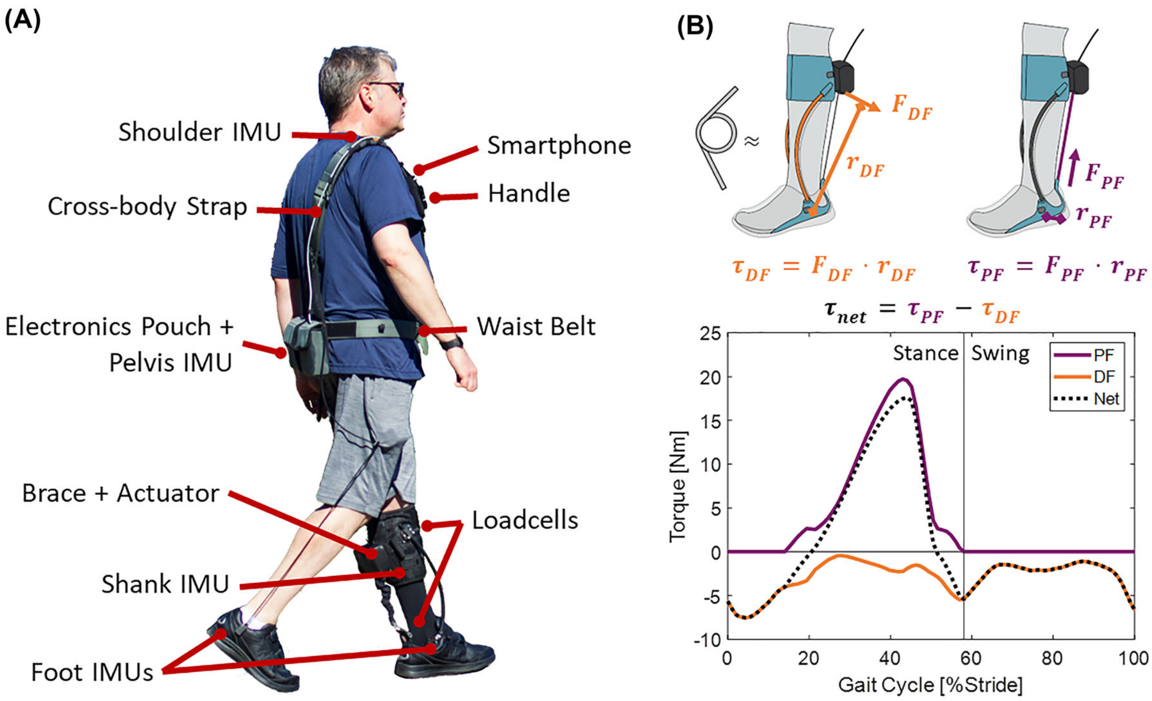

FIGURE 2 Community ankle exosuit overview. (A) The exosuit was designed to be independently donned and used by the participants in the community. (B) Physical compliant rods provided passive dorsiflexion ankle torque. Active actuator provided plantarflexion torque. The exosuit control applied a net torque at the ankle by modulating the plantarflexion torque while accounting for the torque from passive dorsiflexion. Abbreviations: DF, dorsiflexion; IMU, inertial measurement units; PF, plantarflexion. Equation symbols: *F*, force; τ, torque; *r*, moment arm.

4-week unsupervised community walking program

Participants were asked to perform the program for a total of 4 weeks that, due to holidays or weather, did not have to be consecutive. The “gap weeks” were coordinated between the research team and participants. During each week, participants were instructed to walk 3–5 times but were not instructed on how to structure their week except that no more than one session should be performed each day. The maximum walking duration was 60 min per session. No minimum walking time was set (Figure 1, Supporting Text). Participant session activity was facilitated through a mobile device custom application which performed check-in/out procedures, started/stopped sessions, and logged and reported sessions to the research team (Figures S5, S6, and Supporting Text).

During walking, the exosuit applied assistance with an intermittent schedule oscillating between high assistance (25% body weight) and low assistance (5% body weight) every 2 min, with 30 s linear transition in between. Participants were encouraged to maintain their gait pattern when the exosuit was in low assistance. Progressively challenging practice conditions were posited to enhance motor learning.[37]

Lab-based biomechanical evaluation

We performed a lab-based, pre-training evaluation (PRE) within 7 days before the 4-week community walking program and a lab-based, post-training evaluation (POST) within 7 days after the program. For both PRE and POST, the participant completed the same order of conditions and breaks were given between trials (Figure 1). No more than 60 min of walking was completed within the 3-h period. During evaluations in the lab, we collected motion capture (120 Hz, Qualysis, Gothenburg, Sweden) and measured ground reaction forces (GRF) during overground and split belt treadmill walking (1200 Hz, Bertec, Columbus OH, USA).

6-min walk tests

Two 6-min walk tests were conducted in a 30-meter hallway. The order was No-Suit (NS) followed by Active Exosuit.

No-suit lab evaluation

Lab evaluation was first performed without the suit (NS). Participants completed three 10-meter walk tests (10 MWT) at comfortable walking speed (cws) followed by three 10 MWTs at fast walking speed (fws). Next, participants walked for 2 min on the instrumented treadmill at 115% of their 10 MWT NS cws. The 115% NS cws was meant to assess participants' walking ability and gait biomechanics at a speed that was considered challenging at PRE. The same 115% NS cws from the PRE was also used in POST to provide matched speed comparison.

Exosuit lab evaluation

Participants then donned the exosuit. With the exosuit active (EXO), the participant completed a 2-min walk on the treadmill at the same

115% NS cws. Participants completed three exosuit-assisted 10 MWTs at cws followed by three 10 MWTs at fws.

Overground data for training model

Finally, participants completed up to 20 additional 10-meter overground passes with the exosuit active. The instruction was to mimic the walking speed in the community where the participants maintained RPE less than 12. These data were used in the development of the propulsion estimation model.

Remote monitoring of community walking propulsion during cREAL

We developed a learning-based model to monitor participants' paretic propulsion in the community using inertial measurement units (IMUs) on the paretic foot, paretic shank, and pelvis. With PRE and POST IMU data as input and anterior-posterior GRF (AP-GRF) data as output, the model was first trained with the treadmill walking data of all participants. Then, instead of directly using the trained model, the model was further fine-tuned for each participant with overground walking data by leveraging the transfer learning technique (Figures 3A,B, S7, and Supporting Text).

Primary outcome measurements

Orthotic effect of community exosuit assistance on propulsion

In PRE and POST, we measured the participants' within-session change in peak paretic propulsion while walking on the treadmill with EXO compared to NS (Figure 4A). We define this immediate effect of exosuit assistance on paretic propulsion as the orthotic effect.[38]

Therapeutic effect of cREAL walking program on propulsion

We measured the change in participants' peak paretic propulsion during NS treadmill walking in POST compared to NS treadmill walking in the PRE (Figure 4B). We define this change in unassisted paretic propulsion following the 4-week community walking program as the therapeutic effect.

Therapeutic effect of cREAL walking program on number of daily steps

Participants were asked to wear a step counter (wGT3X-BT, ActiGraph, USA) to record their daily step counts. We compared the steps in the week before PRE to the steps taken in the week following POST. We reported on the three participants who were compliant as one participant was not compliant in wearing the device.

Statistical analysis

We used the Anderson–Darling test to check for the normality of the peak-paretic propulsion data for each participant and condition. For normally distributed data, we used a *t*-test for evaluating orthotic and therapeutic effects. When the normality test was rejected, we used the Wilcoxon Rank Sum test and explicitly indicated its use when statistics are reported. We used least-squares regressions to compare relationships between biomechanical outcomes. For the evaluation of the propulsion estimation model, we used root mean squared error (RMSE) to show the accuracy between predicted and ground truth AP-GRF and calculated the coefficient of determination (R^2 score). To evaluate the agreement between lab-measured peak propulsion and model-based community estimates, we used two-way mixed effect, absolute agreement, single rater intraclass correlation coefficients with an alpha value of 0.05.[39,40]

We used Pearson Correlation Coefficient to evaluate correlations for changes in peak propulsion with EXO between (1) PRE-to-POST treadmill walking and (2) first-to-last-week community walking.

RESULTS

Participant demographics and baseline assessments

The four recruited participants (P1–P4) were in the chronic stage of recovery at 10, 8, 16, and 15 years post-stroke, respectively (Table 1). The average baseline 10-meter cws was 1.12, 1.62, 1.07, and 1.36 m s^{-1} for P1–P4 (Table 1).

Despite all participants being unlimited community walkers, there was variation in the severity of functional and biomechanical deficits for the four participants. In functional tests where a higher score indicates less impairment, P1–P4 had Fugl–Meyer lower-extremity motor subscores of 26, 30, 25, and 32 (out of 34) and Functional Gait Assessment scores of 18, 29, 22, and 21 (out of 30) (Table 1). In a pre-training assessment, we measured the paretic and nonparetic propulsion on the treadmill at 115% cws. The paretic impulse symmetry was 19.5%, 38.0%, 42.0%, and 30.0% (Table 1), ranging from severe to moderate hemiparesis.[10]

As measured by the upper-extremity Fugl–Meyer hand subsection,[41,42] P1–P4, respectively, had a paretic hand function of 13, 13, 0, and 14 (out of 14).

Community ankle exosuit

The average peak DF assistance provided to P1–P4 during treadmill walking was 0.9, 3.3, 10.4, and 5.5 Nm. The design enabled post-stroke

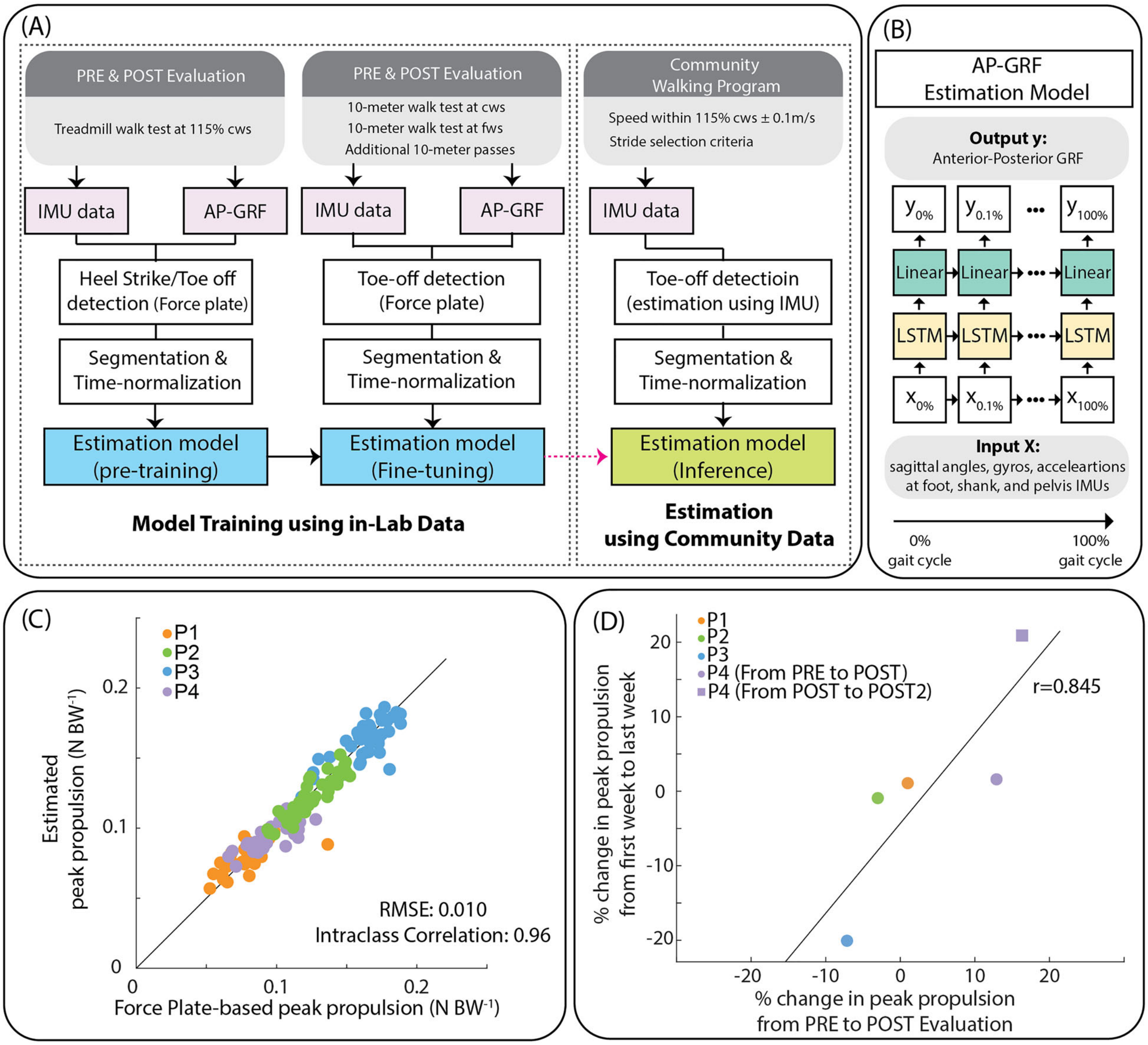

FIGURE 3 Propulsion estimation model and results. (A) Model training process. We pre-trained the learn-based model using across-participants treadmill data collected during PRE and POST evaluations. We then fine-tuned individualized models with overground data of each participant. We used the trained model to estimate anterior-posterior ground reaction force (AP-GRF) on community data. (B) Propulsion model. It takes sagittal angles, sagittal gyros, and 3-axes accelerations from inertial measurement units on foot, shank, and pelvis as an input to predict AP-GRF. We used long-short term memory (LSTM) to train the model. (C) Error of estimated peak propulsion in root mean squared error and intraclass correlation compared with force-plate-measured peak propulsion obtained during overground walking in lab-based evaluations. (D) Pearson correlation coefficients between in-lab changes and propulsion changes in the community. Abbreviations: cws, comfortable walking speed; fws, fast walking speed; IMU, inertial measurement units; N BW^{-1}, newton per body weight; RMSE, root mean squared error.

TABLE 1 Participant baseline characteristics

Participant	Age (years)	Years post CVA	CVA side/type	FGA (/30) Higher = less impaired	Fugl–Meyer (/34) Higher = less impaired	UE Fugl–Meyer (/14) Higher = less impaired	6 MWT (m)	CWS (m/s)	FWS (m/s)	Paretic impulse symmetry (%)
P1	63	10	R/Hem	18	26	13	444	1.12	1.43	19.5
P2	37	8	L/Hem	29	30	13	536	1.62	2.05	38.0
P3	39	16	R/Unknown	22	25	0	409	1.07	1.35	43.0
P4	49	15	R/Isch	21	32	14	556	1.36	1.88	30.0

Abbreviations: 6 MWT, 6-min walking test; CVA, cerebrovascular accident; CWS, comfortable walking speed; FGA, functional gait assessment; FWS, fast walking speed; Hem, hemorrhagic stroke; Isch, ischemic stroke; L, left; R, right; UE, upper extremity.

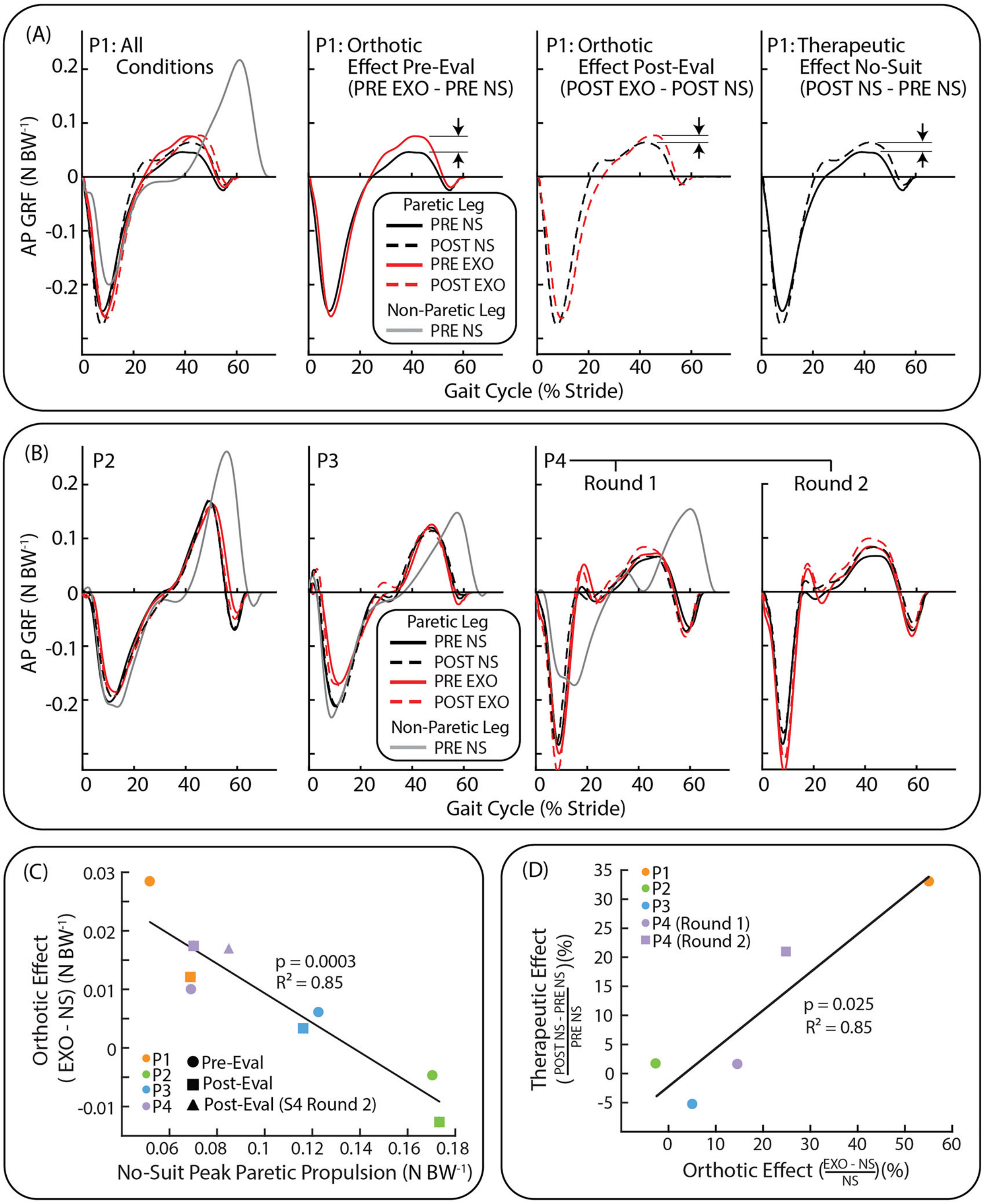

FIGURE 4 Anterior-posterior propulsion during PRE and POST lab evaluations. (A) The results for P1 separated to better highlight the meaning of the outcomes. (B) The outcomes for P2–P4 including the two rounds of the 4-week walking program for P4. Note that POST of Round 1 is equivalent to PRE of Round 2. (C) Relationship between peak paretic propulsion without the suit and the orthotic effect. Data showed that individuals with lower paretic propulsion benefited greater from exosuit assistance. (D) Relationship between the benefit to paretic propulsion received from exosuit assistance and the improvement in propulsion without the suit following the 4-week walking program. Individuals who received greater benefit from the device had improved outcomes following the walking program. Abbreviations: AP-GRF, anterior-posterior ground reaction force; EXO exo-suit active; N BW^{-1}, newton per body weight; NS, no-suit.

participants to don and doff the exosuit independently despite, in some cases, deficits of the paretic hand. The self-donning time for each participant measured in a post evaluation was 3.3, 2.3, 2.8, and 1.9 min for P1–P4.

Implementation of cREAL walking program

The four participants completed the screening and training session and completed the ICC in which they were certified to use the ankle

TABLE 2 Details of 4-week walking program for four post-stroke participants

Participant	Start date	End date	Walking location	Number of sessions	Days between sessions (mean±SD)	Walking time per session (min) (mean±SD)	Number of steps per session (mean±SD)	Average walking speed (m/s) (mean±SD)	Rate of perceived exertions (RPE) (mean±SD)
P1	9/27/2021	10/22/2021	Rural paved road; gravel park path	18	1.4±0.6	51±12	4698±1112	1.26±0.03	9.7±0.4
P2	11/1/2021	1/21/2022	Outdoor track; indoor track	16	5.64±8.26	29±11	2747±1090	1.30±0.04	7.6±0.6
P3	10/12/2021	12/6/2021	Paved sidewalk	16	3.67±3.16	24±12	2509±638	1.24±0.06	7.5±1.1
P4 (Round 1)	9/10/2021	10/6/2021	Urban paved greenway	13	2.2±0.8	32±8	3470±874	1.33±0.03	8.9±1.7
P4 (Round 2)	10/20/2021	11/17/2021	Urban paved greenway	11	2.5±2.2	39±11	4293±1151	1.35±0.05	9.2±1.0

exosuit at their preferred (and research team vetted) community walking location (Table 2). P1 was certified for a rural subdivision road with slight slopes and a gravel park pathway, P2 for an outdoor and indoor track, P3 for a suburban sidewalk, and P4 for an urban greenway. Each location was within proximity of their home or work.

All participants successfully completed the 4-week community walking program with no recorded safety issues. They walked independently and unsupervised with an exosuit in their community setting for 3–5 days per week for a total of 15.5 days on average across participants for the 4 weeks (Table 2). During the community walking program, participants walked 3437 steps per session for 37 min on average (Table 2), estimated by the foot IMUs embedded in the exosuit.[43]

Biomechanical outcomes

Orthotic effect of community exosuit assistance on propulsion

The group-level orthotic effect on participants showed no change due to variability in participant response. P1 and P4 demonstrated an orthotic benefit from ankle exosuit assistance, while P2 and P3 received little to no benefit.

P1 improved peak paretic propulsion by 55% (0.028 N/BW, $p < 0.0001$) and 18% (0.012 N/BW, $p < 0.0001$) for PRE and POST, respectively (Figure 4A,C). In PRE and POST, P2 peak paretic propulsion decreased by 3% (–0.004 N/BW, $p = 0.322$, Wilcoxon Signed Rank) and 7% (–0.013 N/BW, $p < 0.0001$, Wilcoxon Signed Rank), respectively (Figure 4B,C), while P3 peak paretic propulsion orthotic increased by 5% (0.006 N/BW, $p = 0.0025$, Wilcoxon Signed Rank) and 3% (0.003 N/BW, $p = 0.105$), respectively (Figure 4B,C). P4 improved peak paretic propulsion by 15% (0.010 N/BW, $p < 0.0001$) and 25% (0.017 N/BW, $p < 0.0001$) for PRE and POST, respectively (Figure 4B,C). In the post-evaluation following the second 4-week community walking program (POST2), P4 improved peak paretic propulsion by 20% (0.017 N/BW, $p < 0.0001$).

The orthotic effect had a strong negative relationship ($p = 0.0003$; $R^2 = 0.85$) with NS peak paretic propulsion (Figure 4C). That is, participants with lower baseline peak paretic propulsion tended to have higher immediate benefit from the exosuit relative to the higher propulsion participants.

Therapeutic effect of cREAL walking program on propulsion

The group-level therapeutic effect also showed no change due to variability in participant response. P1 had a therapeutic benefit, while P2 and P3 had little to no benefit. P4, who completed two 4-week walking programs, received little benefit after the first 4 weeks and a significant benefit after the second.

P1's therapeutic effect on peak paretic propulsion was 33% (0.017 N/BW; $p < 0.0001$) (Figure 4A,D). Conversely, P2 peak paretic propulsion increased by 2% (0.003 N/BW; $p = 0.04$), and P3 peak paretic propulsion decreased by 5% (–0.0064 N/BW; $p = 0.001$) comparing PRE to POST (Figure 4B,D). P4 received no therapeutic benefit (2%; 0.001 N/BW; $p = 0.53$) following the first 4-week program. However, from the beginning of the second 4-week program (POST) to the end (POST2), P4 had a significant therapeutic benefit where peak paretic propulsion increased by 21% (0.014 N/BW; $p < 0.0001$) (Figure 4B,D).

Participants' therapeutic effect had a strong positive relationship with the orthotic effect directly prior to the community walking program ($n = 5$ [two samples for P4; one sample each for P1, P2, and P3]; $p = 0.026$; $R^2 = 0.85$) (Figure 4D).

Therapeutic effect of cREAL walking program on number of daily steps

Compared to the week prior to the walking program, P1 increased daily step count in the week after the 4-week walking program by 3449 steps/day (to 10,291 steps/day). P2 had a decrease of 7200 steps/day following the program (this was attributed to weather—see limitation).

P3 was not compliant at wearing the step counter, so data were not available for this participant. P4 increased daily step count by 4553 steps/day (to 9720 steps/day).

Remote monitoring of community walking propulsion during cREAL

The learning-based model had an RMSE of within 1% comparing between the estimated peak paretic propulsion and the ground truth peak paretic propulsion measured using overground force plates data during PRE/POST (intraclass correlation coefficient = 0.96) (Figure 3C).

Changes in participants' estimated propulsion from the first to last week of community walking from the trained model strongly correlated with the changes in in-lab exosuit-assisted peak paretic propulsion from PRE to POST[44] (Pearson correlation coefficient, r = 0.845) (Figure 3D).

DISCUSSION

Exosuit-assisted community walking for individuals post-stroke offers exciting potential for the future of rehabilitation in which the benefits to proper joint mechanics from exosuit assistance are combined with the massed practice of independent community walking. In this study, we demonstrated the feasibility of the cREAL walking program incorporating screening and training, an ICC, and a 4-week community walking program (Figure 1). Using the community ankle exosuit we designed for this study, four out of four participants safely completed the 4-week independent walking program.

Only two out of four participants showed improvements in orthotic and therapeutic propulsive benefits and functional benefits from the cREAL program (Figure 4). Interestingly, these were the two participants with the low paretic propulsion (LPP) at the pre-training evaluation. Because of the small sample size and inconsistent group effect, we chose to discuss biomechanical and functional outcomes focused on the LPP participants who had a positive outcome while giving insights into possible reasons for the inconsistent results from other participants.

Biomechanical and functional outcomes of cREAL

The two LPP participants had an orthotic benefit in which peak paretic propulsion was improved by 36.5% (P1) and 20.0% (P4) with EXO compared to NS (Figure 4). This level of orthotic benefit for the two LPP participants was at or above average compared to the 22% ± 45%[16] and 38% ± 32%[18] from past studies that applied similar assistance profiles.

The two LPP participants also had a therapeutic benefit in which they improved their NS paretic propulsion by 33% (P1: first 4 weeks) and 21% (P4: second 4 weeks) after the completion of the cREAL program (Figure 4). These outcomes are on par with a 24% propulsion improvement reported from a study in which a single participant completed high-intensity, task-specific, and progressively challenging walking practice with an exosuit for five daily 30-min sessions with a physical therapist.[15] We could not compare our therapeutic benefit to nonexosuit-based community walking programs as those results are primarily focused on walking speed and did not report changes in propulsion.[2,3] In contrast, we did not seek to improve walking speed and in fact, we deliberately asked participants to limit exertion for safety. Our program focused on training of proper gait mechanics during independent moderate walking in the community. This differs from other nonexosuit community studies that have focused on walking speed; however, they are usually accompanied with traditional high-intensity, in-clinic programs[2,3] and require the physical therapist to be present for community walking sessions.

The two LPP participants improved walking engagement as measured by step count. The increase in daily steps by 4001 steps/day on average in the week following the study compared to the week prior to the study was meaningful considering an expected improvement of 900–1200 steps/day for high-intensity post-stroke walking interventions and 0–500 steps/day for conventional intervention.[12,27,28,45] Furthermore, with the increase in step counts, the two LPP participants were taking 10,000 steps/day on average after the program. This number is not only higher than the suggested 6000 steps/day for individuals post-stroke,[33] but also on par with the suggested 7000–13,000 steps/day for healthy young adults.[34] Although we lack a control group, the community walking program with massed exosuit-assisted stepping practice likely contributed to the increase in steps/day from the two participants following the program. A past study has shown a positive relationship between intensive stepping training and improved daily stepping.[45]

In total, the therapeutic effect of improved propulsion and increased step count suggests the potential for a cREAL rehabilitation program. The improved propulsion without assistance from a device represents an improvement in the participant's innate ability to generate forward propulsion,[13,15] while the increase in the number of steps is important because limited walking can limit motor function recovery[45] and is closely related to the recurrence of additional stroke events.[33]

Relationship between participant biomechanics and cREAL benefits

Our regression analysis suggests that the orthotic benefit that the LPP participants received was related to their baseline inability to generate forward propulsion from the paretic leg (Figure 4). This result aligns with a previous study[16] reporting that participants with lower walking speed could achieve better propulsion symmetry with ankle exosuit assistance.

It was also interesting to find that the therapeutic benefit that participants received from the cREAL walking program was significantly related to the orthotic benefit they could extract from the device (Figure 4). A potential explanation is that the exosuit helps participants achieve proper ankle mechanics during training in the community and this training transfers to improved propulsion without the suit.

These preliminary relationships among baseline paretic propulsion, orthotic benefit, and therapeutic benefit can provide guidance for researchers designing walking program studies. For example, our results would suggest that a cREAL program that wants to provide maximum benefit to participants should recruit community walking participants with LPP and who can similarly derive propulsive benefit from the exosuit.

However, this guidance is constrained to our study design and assistive device. High paretic propulsion (HPP) individuals did not benefit greatly from the assistance prescribed in this study, but that should not imply that HPP individuals cannot receive benefit from assistive devices. Indeed, Awad et al.[46] provided PF assistance with functional electrical stimulation (FES) rather than an exosuit and found that HPP participants rather than LPP could benefit more from the assistance in terms of walking speed.[46] Although a direct comparison of our study results with Awad et al.[46] is difficult (i.e., evaluating propulsion in this study vs. evaluating walking speed in Awad et al.[46] due to a different range of participant demographics), these studies together suggest that different assistance/rehabilitation strategies (e.g., exosuit vs. FES) should be used depending on the participant's needs (e.g., LPP vs. HPP). These findings add to the growing evidence suggesting the importance of customizing rehab therapy[47,48] and individualizing exosuit assistance[49–51] to the needs of the individual.

An additional consideration on the study design is that this study did not explicitly focus on training the individuals to achieve maximum orthotic benefit. Training has been shown to account for half of the metabolic benefit that a neurotypical wearer gets from an exosuit[52] and there is the potential that LPP and HPP individuals could have been trained to achieve improved orthotic benefit. Future studies could explore whether additional exposure and training in advance of program participation increases the benefits of the community walking program.

Additional contributions of the cREAL program

Community exosuit system

To the best of our knowledge, this exosuit is the first to provide active PF and passive DF assistance.[53–55] The passive DF assistance ensures that in any electronic failures, the system is still able to maintain gait stability as an ankle-foot orthosis.[56]

The assistance profile of the ankle exosuit in this study was the same for all participants and was based on the assistance profile from prior studies[16,17] (Figure S1). Nevertheless, previous studies show that individualized assistance profiles could lead to better orthotic benefit compared to a generic profile.[49,51] There may be a potential to develop a controller that generates individualized assistance profiles to maximize the therapeutic benefit in the community walking program.

Massed stepping practice

One of the suspected benefits of the community walking program was the ability to enable massed stepping to promote improved locomotor outcomes.[57] The 3437 ± 1316 steps that our participants took in an average 37-min session were higher than in-clinic training programs with similar training times.[27,57] One study with 40-min training sessions in a clinic reported that participants walked on average 2460 steps per session[57] for conventional therapy and 2826 for high-intensity training. Another study with 1-h in-clinic training sessions reported that participants walked 2887 steps per session.[27] The mobile application we developed displayed walking time and number of steps at the end of each session. Although we did not evaluate the impact of immediate feedback in our study, such feedback on step activity may influence participants' motivation to walk[58] and should be explored in future research.

Diverse and challenging environments

In addition to providing massed walking practice, another benefit of the community walking program is that participants may encounter environments with diverse terrains, inclines, and distractions compared to a clinical setting. Studies based on in-clinic training reported that training under variable and challenging environments can improve locomotor function and symmetry[27,28,30] due to increased requirements for neuromuscular coordination and postural control.[27,28,31] However, artificial variation created in clinical settings may not sufficiently replace complex situations presented in outdoor environments.[59] By walking in the community, the cREAL program offers the opportunity to train in diverse contextual environments that are not available in the clinic.[32]

Community propulsion model

Our learning-based propulsion estimation model shows the potential for progress tracking during a community walking program. The high correlation between the changes in the community and in the PRE and POST sessions suggests that our estimator can track trends in walking propulsion outside the lab environment. These community estimates can potentially be used as feedback to motivate participants or inform physical therapists on the ongoing progress of a community rehabilitation program. Additional details on the implementation of the model relative to other approaches are provided in the Supporting Text.

Limitations

This study was an early-stage experiment. The interpretation of the outcomes from this study should consider both the sample size and the large amount of variability that exists in the people post-stroke and in community walking. Nevertheless, outcomes for some participants were promising, and the results demonstrated the potential for exosuits in post-stroke community rehabilitation.

With safety as the priority, the four participants recruited were classified as unlimited community walkers and did not represent the full extent of the heterogeneous post-stroke populations. Further investigation is needed to better understand the effect of the community walking program on participants with greater and lesser walking function. Furthermore, the four participants had experienced a similar ankle exosuit before the study, had used it safely previously, and they were motivated to participate and use robotic devices in their community. These factors could likely affect the outcomes, but the exact bias on the measured orthotic and therapeutic effect was unknown.

Our walking program 4-week interval was in line with the time interval and session count of previous community studies without exosuit assistance,[22] high-intensity training clinical studies,[27] or exosuit augmented clinical gait training studies.[13] Given the results from these studies, the 4 weeks was expected to provide enough practice such that a therapeutic effect would be detectable if it existed. However, more mature clinical stroke-rehabilitation studies can last for upward of 10 weeks and 40 sessions.[27,57] Participants in future cREAL studies would benefit from additional study length as evidenced by the improvement in P4 therapeutic effect during weeks 5–8.

There was no control group for this study similar to recent preliminary exosuit training studies[13,15] and community studies.[22–25,27,28] Multiple groups would be ideal to help separate out the relative contribution from community walking and exosuit assistance, and the logistics of performing such a study is daunting without some understanding of expected outcomes. Additionally, despite promising therapeutic benefit from two participants, the permanency of the therapeutic benefit received by participants was unknown as we did not perform follow-up sessions.[27] Our work was an initial investigation into the implementation and outcomes from an exosuit-assisted study and our results should be used to inform larger studies with control groups and follow-up evaluations.

There were many external environmental variables in the study that may affect the results. Each participant was certified to walk at a convenient location near their home or workplace, ranging from an indoor track to a paved sidewalk with slight slopes. Weather and time of year was also a large factor that likely influenced participants' motivation to walk. The first participant began in September and the final participant finished in January. Due to weather conditions and holiday schedules, participants were permitted to complete a total of 4 weeks that did not have to be consecutive, resulting in different durations and intensities to finish the program. Future community studies should consider these factors and evaluate how they affect outcomes.

CONCLUSION

This paper describes the development and evaluation of a cREAL program that begins to close the gap between exosuit-assisted, in-clinic therapy and community walking training. This study provides initial evidence that individuals post-stroke can independently and safely use an exosuit designed for an extended 4-week community walking program. Furthermore, the study demonstrates that some individuals can derive substantial therapeutic benefit from an exosuit-assisted community walking program.

Future work should leverage the design and outcomes from this study and evaluate the effectiveness of the cREAL program in a larger clinical study. Furthermore, given the ability to monitor participant performance in real-time, future studies should aim to incorporate physical therapist intervention and guidance over the course of a community walking program.

AUTHOR CONTRIBUTIONS

All authors contributed to the conceptualization of the study. R.W.N., C.K.C., A.E.E., D.O., P.M., B.Q., J.G., and V.Q. contributed to the development of the community exosuit. R.W.N., C.K.C., L.B., A.E.E., D.O., T.B., and C.J.W. developed the methodology for the cREAL program and study. R.W.N., C.K.C., and D.K. contributed to the development of the propulsion model. R.W.N., C.K.C., D.K., L.B., J.G., N.C.W., and T.B. conducted the experiments. R.W.N., C.K.C., and D.K. analyzed and interpreted the data. L.N.A., T.E., and C.J.W. contributed to funding acquisition. R.W.N., C.K.C., D.K., and C.J.W. prepared the manuscript. All authors revised and approved the manuscript.

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COMPETING INTERESTS

Patents describing the exosuit components documented in this article have been filed with the U.S. Patent Office by Harvard University, and C.J.W. is an inventor. C.J.W. is a paid consultant to ReWalk Robotics. The remaining authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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